

Applicant: Smith *et al.*
Application No.: 09/845,157
Filed: May 1, 2001
For: **Thermostable Reverse Transcriptases and Uses Thereof**

Due Date: None
Art Unit: 1623
Examiner: To be assigned
Docket: 0942.5040001
Atty: RWE/MTT

When receipt stamp is placed hereon, the USPTO acknowledges receipt of the following documents:

1. SKG&F Cover Letter (*in duplicate*);
2. Information Disclosure Statement (*in duplicate*);
3. List of references cited on Form PTO-1449 (15 sheets);
4. A copy of each reference cited on Form PTO-1449 (83 references); and
5. One (1) Return Postcard.



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Smith *et al.*

Appl. No. 09/845,157

Filed: May 1, 2001

For: **Thermostable Reverse
Transcriptases and Uses Thereof**

Confirmation No. 2674

Art Unit: 1623

Examiner: To be assigned

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Information Disclosure Statement

Commissioner for Patents
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. A copy of each of these documents is provided.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that had been cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

The Examiner's attention is directed to the following co-pending U.S. Patent Applications:

09/677,574, filed October 3, 2000;

09/808,124, filed March 15, 2001; and

09/902,741, filed July 12, 2001,

which are directed to related technical subject matter. Pursuant to 37 C.F.R. §1.98 (a) (2), legible copies of these applications are provided herein as documents AM15, AN15, and AO15, respectively. The identification of these U.S. Patent Applications is not to be construed as a waiver of secrecy as to those applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036. A duplicate copy of this pleading is enclosed.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Robert W. Esmond
Attorney for Applicants
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Date: Nov. 2, 2001

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U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	5,244,797	09/14/1993	Kotewicz <i>et al.</i>	435	194	03/18/1991
	AB1	B1 5,244,797	08/25/1998	Kotewicz <i>et al.</i>	435	194	03/18/1991
	AC1	5,405,776	04/11/1995	Kotewicz <i>et al.</i>	435	252.33	01/24/1992
	AD1	B1 5,405,776	10/01/1996	Kotewicz <i>et al.</i>	435	194	01/24/1992
	AE1	5,668,005	09/16/1997	Kotewicz <i>et al.</i>	435	194	03/12/1996
	AF1	6,063,608	05/16/2000	Kotewicz <i>et al.</i>	435	194	02/10/1997
	AG1	6,136,582	10/24/2000	Gao <i>et al.</i>	435	194	01/20/1998
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AI1	WO 98/47912	10/29/1998	WIPO			Yes No
	AJ1	WO 99/10366	03/04/1999	WIPO			Yes No
	AK						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AL	1	Arion, D., <i>et al.</i> , "The K65R Mutation Confers Increased DNA Polymerase Processivity to HIV-1 Reverse Transcriptase," <i>J. Biol. Chem.</i> 271:19860-19864, American Society for Biochemistry and Molecular Biology (1996)
	AM	1	Bakhanashvili, M., and Hizi, A., "The fidelity of the reverse transcriptases of human immunodeficiency viruses and murine leukemia virus, exhibited by the mispair extension frequencies, is sequence dependent and enzyme related," <i>FEBS</i> 319:201-205, Elsevier Science Publishers B.V. (1993)
	AN	1	Bakhanashvili, M., and Hizi, A., "A possible role for cysteine residues in the fidelity of DNA synthesis exhibited by the reverse transcriptases of human immunodeficiency viruses type 1 and type 2," <i>FEBS</i> 304:289-293, Elsevier Science Publishers B.V. (1992)
	AO	1	Bakhanashvili, M., <i>et al.</i> , "Mutational studies of human immunodeficiency virus type 1 reverse transcriptase: the involvement of residues 183 and 184 in the fidelity of DNA synthesis," <i>FEBS Lett.</i> 391:257-262, Elsevier Science Publishers B.V. (1996)
	AP	1	Bakhanashvili, M., and Hizi, A., "Fidelity of the RNA-Dependent DNA Synthesis Exhibited by the Reverse Transcriptases of Human Immunodeficiency Virus Types 1 and 2 and of Murine Leukemia Virus: Mismatch Extension Frequencies," <i>Biochem.</i> 31:9393-9398, American Chemical Society (1992)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
	AL	2	Barnes, W.M., "The fidelity of <i>Taq</i> polymerase catalyzing PCR is improved by an N-terminal deletion," <i>Gene</i> 112:29-35, Elsevier Science Publishers B.V. (1992)
	AM	2	Basu, S., <i>et al.</i> , "Sulphydryl groups in the template-primer-binding domain of murine leukemia virus reverse transcriptase," <i>Biochem. J.</i> 296:577-583, The Chemical Society, London (1993)
	AN	2	Bebenek, K., <i>et al.</i> , "Reduced Frameshift Fidelity and Processivity of HIV-1 Reverse Transcriptase Mutants Containing Alanine Substitutions in Helix H of the Thumb Subdomain," <i>J. Biol. Chem.</i> 270:19516-19523, American Society for Biochemistry and Molecular Biology (1995)
	AO	2	Bebenek, K., <i>et al.</i> , "The Fidelity of DNA Synthesis Catalyzed by Derivatives of <i>Escherichia coli</i> DNA Polymerase I," <i>J. Biol. Chem.</i> 265:13878-13887, The American Society for Biochemistry and Molecular Biology (1990)
	AP	2	Ben-Artzi, H., <i>et al.</i> , "Characterization of the double stranded RNA dependent RNase activity associated with recombinant reverse transcriptases," <i>Nucleic Acids Res.</i> 20:5115-5118, Oxford University Press (1992)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AL	<u>3</u>	Berger, S.L., <i>et al.</i> , "Reverse Transcriptase and Its Associated Ribonuclease H: Interplay of Two Enzyme Activities Controls the Yield of Single-Stranded Complementary Deoxyribonucleic Acid," <i>Biochemistry</i> 22:2365-2372, The American Chemical Society (1983)
	AM	<u>3</u>	Blain, S.W., and Goff, S.P., "Effects on DNA Synthesis and Translocation Caused by Mutations in the RNase H Domain of Moloney Murine Leukemia Virus Reverse Transcriptase," <i>J. Virol.</i> 69:4440-4452, The American Society for Microbiology (1995)
	AN	<u>3</u>	Caliendo, A.M., <i>et al.</i> , "Effects of Zidovudine-Selected Human Immunodeficiency Virus Type 1 Reverse Transcriptase Amino Acid Substitutions on Processive DNA Synthesis and Viral Replication," <i>J. Virol.</i> 70:2146-2153, The American Society for Microbiology (1996)
	AO	<u>3</u>	Carroll, S.S., <i>et al.</i> , "A Mutant of DNA Polymerase I (Klenow Fragment) with Reduced Fidelity," <i>Biochem.</i> 30:804-813, American Chemical Society (1991)
	AP	<u>3</u>	Carter, P. and Wells, J.A., "Engineering Enzyme Specificity by 'Substrate-Assisted Catalysis,'" <i>Science</i> 237:394-399, American Association for the Advancement of Science (1987)

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	AL	<u>4</u>	Chen, Y., and Marion, P.L., "Amino Acids Essential for RNase H Activity of Hepadnaviruses Are Also Required for Efficient Elongation of Minus-Strand Viral DNA," <i>J. Virol.</i> 70:6151-6156, The American Society for Microbiology (1996)
	AM	<u>4</u>	Chowdhury, K., <i>et al.</i> , "Elucidation of the Role of Arg 110 of Murine Leukemia Virus Reverse Transcriptase in the Catalytic Mechanism: Biochemical Characterization of Its Mutant Enzymes," <i>Biochemistry</i> 35:16610-16620, American Chemical Society (1996)
	AN	<u>4</u>	Creighton, S., <i>et al.</i> , "Base Mismatch Extension Kinetics," <i>J. Biol. Chem.</i> 267:2633-2639, American Society for Biochemistry and Molecular Biology (1992)
	AO	<u>4</u>	DeStefano, J.J., <i>et al.</i> , "Parameters that influence processive synthesis and site-specific termination by human immunodeficiency virus reverse transcriptase on RNA and DNA templates," <i>Biochimica et Biophysica Acta</i> 1131:270-280, Elsevier Science Publishers B.V. (1992)
	AP	<u>4</u>	Diaz, L., and DeStefano, J.J., "Strand transfer is enhanced by mismatched nucleotide at the 3' primer terminus: a possible link between HIV reverse transcriptase fidelity and recombination," <i>Nucleic Acids Res.</i> 24:3086-3092, Oxford University Press (1996)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AL	<u>5</u>	Drosopoulos, W.C., and Prasad, V.R., "Increased Polymerase Fidelity of E89G, a Nucleoside Analog-Resistant Variant of Human Immunodeficiency Virus Type 1 Reverse Transcriptase," <i>J. Virol.</i> 70:4834-4838, The American Society for Microbiology (1996)
	AM	<u>5</u>	Drosopoulos, W.C., and Prasad, V.R., "Increased Misincorporation Fidelity Observed for Nucleoside Analog Resistance Mutations M184V and E89G in Human Immunodeficiency Virus Type 1 Reverse Transcriptase Does Not Correlate with the Overall Error Rate Measured In Vitro," <i>J. Virol.</i> 72:4224-4230, The American Society for Microbiology (1998)
	AN	<u>5</u>	Eckert, K.A., and Kunkel, T.A., "Fidelity of DNA synthesis catalyzed by human DNA polymerase α and HIV-1 reverse transcriptase: effect of reaction pH," <i>Nucleic Acids Res.</i> 21:5212-5220, Oxford University Press (1993)
	AO	<u>5</u>	Eger, B.T., <i>et al.</i> , "Mechanism of DNA Replication Fidelity for Three Mutants of DNA Polymerase I: Klenow fragment KF(oxo+), KF(polA5), and KF(exo-)," <i>Biochem.</i> 30:1441-1448, American Chemical Society (1991)
	AP	<u>5</u>	Feng, J.Y., and Anderson, K.S., "Mechanistic Studies Examining the Efficiency and Fidelity of DNA Synthesis by the 3TC-Resistant Mutant (184V) of HIV-1 Reverse Transcriptase," <i>Biochemistry</i> 38:9440-9448, The American Chemical Society (July 1999); Published on the web on June 30, 1999.

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	AL	<u>6</u>	Finston, W.I. and Champoux, J.J., "RNA-Primed Initiation of Moloney Murine Leukemia Virus Plus Strands by Reverse Transcriptase In Vitro," <i>J. Virology</i> 51:26-33, American Society for Microbiology (1984)
	AM	<u>6</u>	Gao, G., and Goff, S.P., "Replication Defect of Moloney Murine Leukemia Virus with a Mutant Reverse Transcriptase That Can Incorporate Ribonucleotides and Deoxyribonucleotides," <i>J. Virol.</i> 72:5905-5911, The American Society for Microbiology (1998)
	AN	<u>6</u>	Gerard, G.F., <i>et al.</i> , "cDNA Synthesis by Cloned Moloney Murine Leukemia Virus Reverse Transcriptase Lacking RNase H Activity," <i>Focus</i> 11:66-69, Life Technologies, Inc. (1989)
	AO	<u>6</u>	Gerard, G.F., <i>et al.</i> , "Influence on Stability in <i>Escherichia coli</i> of the Carboxy-Terminal Structure of Cloned Moloney Murine Leukemia Virus Reverse Transcriptase," <i>DNA</i> 5:271-279, Mary Ann Liebert, Inc. (1986)
	AP	<u>6</u>	Gerard, G., <i>et al.</i> , "cDNA Synthesis by Moloney Murine Leukemia Virus RNase H-Minus Reverse Transcriptase Possessing Full DNA Polymerase Activity," <i>Focus</i> 14:91-93, Life Technologies, Inc. (1992)

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	AL	<u>7</u>	Gerwin, B.I., <i>et al.</i> , "Mutant of B-Tropic Murine Leukemia Virus Synthesizing an Altered Polymerase Molecule," <i>J. Virology</i> 31:741-751, The American Society for Microbiology (1979)
	AM	<u>7</u>	Goff, S.P., "Retroviral Reverse Transcriptase: Synthesis, Structure, and Function," <i>J. Acquired Immune Deficiency Syndrome</i> 3:817-831, Raven Press (1990)
	AN	<u>7</u>	Goff, S.P. and Lobel, L.I., "Mutants of murine leukemia viruses and retroviral replication," <i>Biochimica et Biophysica Acta</i> . 907:93-123, Elsevier Science Publishers B.V. (1987)
	AO	<u>7</u>	Goobar-Larsson, L., <i>et al.</i> , "Disruption of a Salt Bridge between Asp 488 and Lys 465 in HIV-1 Reverse Transcriptase Alters Its Proteolytic Processing and Polymerase Activity," <i>Virology</i> 196:731-738, Academic Press (1993)
	AP	<u>7</u>	Götte, M., <i>et al.</i> , "The M184V Mutation in the Reverse Transcriptase of Human Immunodeficiency Virus Type 1 Impairs Rescue of Chain-Terminated DNA Synthesis," <i>J. Virol.</i> 74:3579-3585, The American Society for Microbiology (April 2000)

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	AL	<u>8</u>	Guo, J., <i>et al.</i> , "Defects in Primer-Template Binding, Processive DNA Synthesis, and RNase H Activity Associated with Chimeric Reverse Transcriptases Having the Murine Leukemia Virus Polymerase Domain Joined to <i>Escherichia coli</i> RNase H," <i>Biochemistry</i> 34:5018-5029, The American Chemical Society (1995)
	AM	<u>8</u>	Hamburgh, M.E., <i>et al.</i> , "The influence of 3TC-resistance mutations EB9G and M184V in the human immunodeficiency virus reverse transcriptase on mispair extension efficiency," <i>Nucleic Acids Res.</i> 26:4389-4394, Oxford University Press (1998)
	AN	<u>8</u>	Hite, J.M., <i>et al.</i> , "Factors affecting fidelity of DNA synthesis during PCR amplification of d(C-A) _n -d(G-T) _n microsatellite repeats," <i>Nucleic Acids Res.</i> 24:2429-2434, Oxford University Press (1996)
	AO	<u>8</u>	Hsu, M., <i>et al.</i> , "Higher fidelity of RNA-dependent DNA mispair extension by M184V drug-resistant than wild-type reverse transcriptase of human immunodeficiency virus type 1," <i>Nucleic Acids Research</i> 25:4532-4536, Oxford University Press (1997)
	AP	<u>8</u>	Jin, J., <i>et al.</i> , "Analysis of the Role of Glutamine 190 in the Catalytic Mechanism of Murine Leukemia Virus Reverse Transcriptase," <i>J. Biol. Chem.</i> 274:20861-20868, American Society for Biochemistry and Molecular Biology (July 1999)

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	AL	2	Kaushik, N., <i>et al.</i> , "Role of Glutamine-151 of Human Immunodeficiency Virus Type-1 Reverse Transcriptase in RNA-Directed DNA Synthesis," <i>Biochemistry</i> 36:14430-14438, The American Chemical Society (1997)
	AM	2	Kaushik, N., <i>et al.</i> , "Role of Glutamine 151 of Human Immunodeficiency Virus Type-1 Reverse Transcriptase in Substrate Selection As Assessed by Site-Directed Mutagenesis," <i>Biochemistry</i> 39:2912-2920, The American Chemical Society (March 2000); Published on the web on February 22, 2000.
	AN	2	Kaushik, N., <i>et al.</i> , "Tyrosine 222, a Member of the YXDD Motif of MuLV RT, Is Catalytically Essential and Is a Major Component of the Fidelity Center," <i>Biochemistry</i> 38:2617-2627, The American Chemical Society (March 1999); Published on the web on February 10, 1999.
	AO	2	Kerr, S.G., and Anderson, K.S., "RNA Dependent DNA Replication Fidelity of HIV-1 Reverse Transcriptase: Evidence of Discrimination between DNA and RNA Substrates," <i>Biochemistry</i> 36:14056-14063, The American Chemical Society (1997)
	AP	2	Kim, B., <i>et al.</i> , "Fidelity of Mutant HIV-1 Reverse Transcriptases: Interaction with the Single-Stranded Template Influences the Accuracy of DNA Synthesis," <i>Biochemistry</i> 37:5831-5839, The American Chemical Society (1998); Published on the web on April 9, 1998.

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	AL	10	Kim, B., <i>et al.</i> , "New Human Immunodeficiency Virus, Type 1 Reverse Transcriptase (HIV-1 RT) Mutants with Increased Fidelity of DNA Synthesis," <i>J. Biol. Chem.</i> 274:27666-27673, American Society for Biochemistry and Molecular Biology (September 1999)
	AM	10	Levin, J.G., <i>et al.</i> , "Murine Leukemia Virus Mutant with a Frameshift in the Reverse Transcriptase Coding Region: Implications for <i>pol</i> Gene Structure," <i>J. Virology</i> 51:470-478, American Society for Microbiology (1984)
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	AO	10	Martin-Hernandez, A.M., <i>et al.</i> , "Human immunodeficiency virus type 1 reverse transcriptase: role of Tyr115 in deoxynucleotide binding and misinsertion fidelity of DNA synthesis," <i>EMBO J.</i> 15:4434-4442, Oxford University Press (1996)
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	AM	<u>11</u>	Oude Essink, B.B., <i>et al.</i> , "Increased polymerase fidelity of the 3TC-resistant variants of HIV-1 reverse transcriptase," <i>Nucleic Acids Res.</i> 25:3212-3217, Oxford University Press (1997)
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	AM	<u>12</u>	Prasad, V.R. and Goff, S.P., "Linker insertion mutagenesis of the human immunodeficiency virus reverse transcriptase expressed in bacteria: Definition of the minimal polymerase domain," <i>Proc. Natl. Acad. Sci. USA</i> 86:3104-3108, The National Academy of Sciences of the USA (1989)
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	AO	<u>12</u>	Repaske, R., <i>et al.</i> , "Inhibition of RNase H Activity and Viral Replication by Single Mutations in the 3' Region of Moloney Murine Leukemia Virus Reverse Transcriptase," <i>J. Virology</i> 63:1460-1464, American Society for Microbiology (1989)
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	AL	14	Suzuki, M., et al., "Low Fidelity Mutants in the O-Helix of <i>Thermus aquaticus</i> DNA Polymerase I," <i>J. Biol. Chem.</i> 272:11228-11235, The American Society for Biochemistry and Molecular Biology, Inc. (1997)
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	AN	14	Taube, R., et al., "The fidelity of misinsertion and mispair extension throughout DNA synthesis exhibited by mutants of the reverse transcriptase of human immunodeficiency virus type 2 resistant to nucleoside analogs," <i>Eur. J. Biochem.</i> 250:106-114, FEBS (1997)
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	AL	15	Wainberg, M.A., <i>et al.</i> , "Enhanced Fidelity of 3TC-Selected Mutant HIV-1 Reverse Transcriptase," <i>Science</i> 271:1282-1285, American Association for the Advancement of Science (1996)
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